

STATE OF INDIANA

Request for Information 10-38

INDIANA DEPARTMENT OF ADMINISTRATION

On Behalf Of

The Family and Social Services Administration

Solicitation For:

Services for Indiana Cord Blood Bank

Response Due Date: December 22, 2009

Stephanie Taylor Indiana Department of Administration Procurement Division 402 W. Washington St., Room W478 Indianapolis, IN 46204

REQUEST FOR INFORMATION 10-38

This is a Request for Information (RFI) issued by the Indiana Department of Administration (IDOA) in conjunction with the Family and Social Services Administration (FSSA). This RFI requests responses for services associated with the creation of the Indiana Cord Blood Bank. There will not be a contract resulting directly from this RFI; however, respondents to this RFI will be placed on the list of potential respondents and will receive an announcement of any Request for Proposal (RFP) that may arise from this RFI.

BACKGROUND

FSSA has completed the incorporation of the Indiana Cord Blood Bank, Inc. ("the Bank") as a non-profit corporation with the Indiana Office of the Secretary of State. FSSA is especially interested in procuring services from qualified and experienced organizations to support the Indiana Cord Blood Bank in accordance with House Enrolled Act 1172 (HEA 1172). Indiana Cord Blood Bank intends to partner with an organization that can demonstrate the requisite capabilities, experience, and financial viability to provide the requested services. The Bank will ultimately serve the following objectives: 1) Promote public awareness, 2) Increase supplies of available transplants (and increase minority participation), 3) Increase supplies for research, including sale of non-transplantable units to third parties for research purposes. A summary of the provisions of HEA 1172 is included with this RFI as Exhibit A.

This RFI, a step in the procurement process, has two key objectives: 1) Provide prospective respondents with general information regarding the statewide project and its targeted schedule and 2) Solicit respondent information that will help FSSA in the development of the resulting RFP.

SPECIFIC NEEDS

The RFP process will be open to all respondents regardless of their decision to participate in this RFI. FSSA seeks creative, high-level responses to the RFI components. FSSA is especially interested in receiving the following information from each respondent's RFI submission:

- Respondent's qualifications and related experience necessary to provide the services required per HEA 1172, and comply with all applicable regulations and accreditation requirements
- Ability to meet Federal, State and local regulations for testing/collecting/storing donations including but not limited to:
 - Compliance with Good Tissue Practice (cGTP; Defined in Title 21 Food and Drugs of CFR Part 1271 Subpart D) and applicable Good Manufacturing Practices (cGMPs)
 - Clinical Laboratory Improvement Amendments (CLIA)
 - o Applicable informed consent rules
 - o Confidentiality/HIPAA
 - o Indiana State Licensure for blood centers (Indiana Code 16-41-12)
- Ability to exceed Federal, State and local regulations by pursuing additional

accreditation such as, but not limited to, the following:

- o AABB Accreditation (<u>www.aabb.org</u>)
- Foundation for the Accreditation of Cellular Therapy (FACT) Accreditation
- Qualifications and related experience necessary to manage the following day-to-day operations:
 - o Manage day-to-day activities of banking and storage
 - o Transport donation after collection
 - o Provide and manage a facility for testing, freezing, and storing donation
 - Test donation
 - Collect, log, and manage all data collected (please detail proposed formats, tools, etc.)
- Ability to maintain electronic records:
 - o Please describe what records/documents may be maintained electronically
 - o Please describe respondent's ability to comply with HIPAA requirements
 - Please describe respondent's approach to managing risks arising from data loss, improper access, security breaches etc.
- Ability to work with the Bank's Board of Directors and Advisory Board
- Respondent's anticipated presence in the State of Indiana
- Registration with the National Marrow Donor Program
- Ability to market for donations through outreach/public education
- Ability to market non-transplantable donations for research
- Agreement to meet contractual requirements for any potential RFP
- Demonstration of corporate/financial stability and industry presence
- Comparable project references of similar scope and size

RESPONSES

Firms interested in providing information to FSSA should submit <u>One (1) original</u> <u>printed copy and Ten (10) complete electronic copies on CD-ROM to:</u>

Ms. Stephanie Taylor
Indiana Department of Administration
Procurement Division
402 West Washington Street, Room W468
Indianapolis, IN 46204

Responses must be received no later than **3:00 p.m. Eastern Time** on **Tuesday**, **December 22, 2009**. The outside of the package (envelope or box) should be clearly marked:

"RESPONSE TO REQUEST FOR INFORMATION 10-38"

Any questions regarding this RFI must be submitted to the above address. Questions may also be submitted by fax at (317) 234-1281 or by e-mail to rfp@idoa.in.gov no later than 3:00 p.m. Eastern Time on Tuesday, November 24, 2009. Responses to all questions will be promptly prepared through a cooperative effort of IDOA and FSSA. A copy of

each question and answer will be posted to the State of Indiana website http://www.in.gov/idoa/2788.htm

Inquiries are not to be directed to any staff member of FSSA.

Responses will be considered public information once a Request for Proposal (RFP) is complete. If an RFP is not undertaken, the responses are considered public once the decision is made.

Please note that Ms. Stephanie Taylor is the State's single point of contact for this RFI.

Please note that the usual and customary procedures for selecting a vendor (issuance of an RFP) may follow this RFI. The process will be open to all providers irrespective of their participation or non-involvement in this information-gathering process.

Exhibit A

Summary of HEA 1172 provisions

- Mandates creation of a non-profit entity to form and operate a public cord blood bank in the State of Indiana (the "Bank")
- The Bank will collect donations from patients at "Participating Hospitals" at no cost to donors
- Donations collected by the Bank may consist of:
 - Cord blood
 - o Placenta
 - Tissues extracted from the umbilical cord
- All property rights in donated samples transfer to Bank upon donation
- Units either eligible for transplant or research

Full Text of HEA 1172 available at:

http://www.in.gov/legislative/bills/2008/HE/HE1172.1.html